North Central London
Joint Formulary Committee

Flash Glucose Monitoring (inc. Freestyle Libre®): Position Statement

GPs should not initiate Flash Glucose Monitoring sensors on the NHS.

NHS diabetes specialist teams will assess both new and self-funding patients for the NHS provision of Flash Glucose Monitoring at their next routine follow-up appointment.

New patients will undergo a trial period with Flash Glucose Monitoring. Patients will receive their first 2 months' supply from their NHS diabetes specialist team with prescribing responsibility transferred to GPs thereafter. The assessment of effectiveness of Flash Glucose Monitoring is the responsibility of the NHS diabetes specialist team.

For self-funding patients who meet NHS eligibility and continuation criteria, as assessed by an NHS diabetes specialist, their GPs will be notified for continued prescribing.

Only patients who meet eligibility criteria who are not under the care of an NHS diabetes specialist service need to be referred if requesting or could benefit from Flash Glucose Monitoring.

Flash glucose monitoring is not recommended for patients with type 2 diabetes unless they require haemodialysis.

Flash Glucose Monitoring measures glucose levels via a sensor as an alternative to routine finger-prick blood glucose testing. Blood glucose testing remains necessary for monitoring during acute illness or hypoglycaemic episodes and for 'Group 2' drivers.

Background

- Flash Glucose Monitoring measures glucose levels from a sensor applied to the skin as an alternative to routine finger-prick self-monitoring blood glucose (SMBG) testing. It can produce a near-continuous record of measurements which can be accessed on demand. Flash Glucose Monitoring does not provide real-time continuous glucose monitoring or a hypoglycaemia alarm.
- Flash Glucose Monitoring is not a complete substitute for SMBG testing as finger-prick testing is still required for patients using a bolus calculator, during times of rapidly changing glucose levels (i.e. acute illness), if hypoglycaemia is reported, if impending hypoglycaemia is reported, or if symptoms do not match the system reading. SMBG testing is also required prior to and during driving to meet current DVLA requirements for 'Group 2' drivers (link).
- The NHS England produced national arrangements for funding Flash Glucose Monitoring (link).
- NHS London Procurement Partnership (LPP) and the London Diabetes Clinical Network (LDCN) have worked in collaboration to safely and effectively implement the NHS England Funding statement. This work has subsequently been adapted for use in North Central London; and the full NCL implementation guide is available on the NCL website.

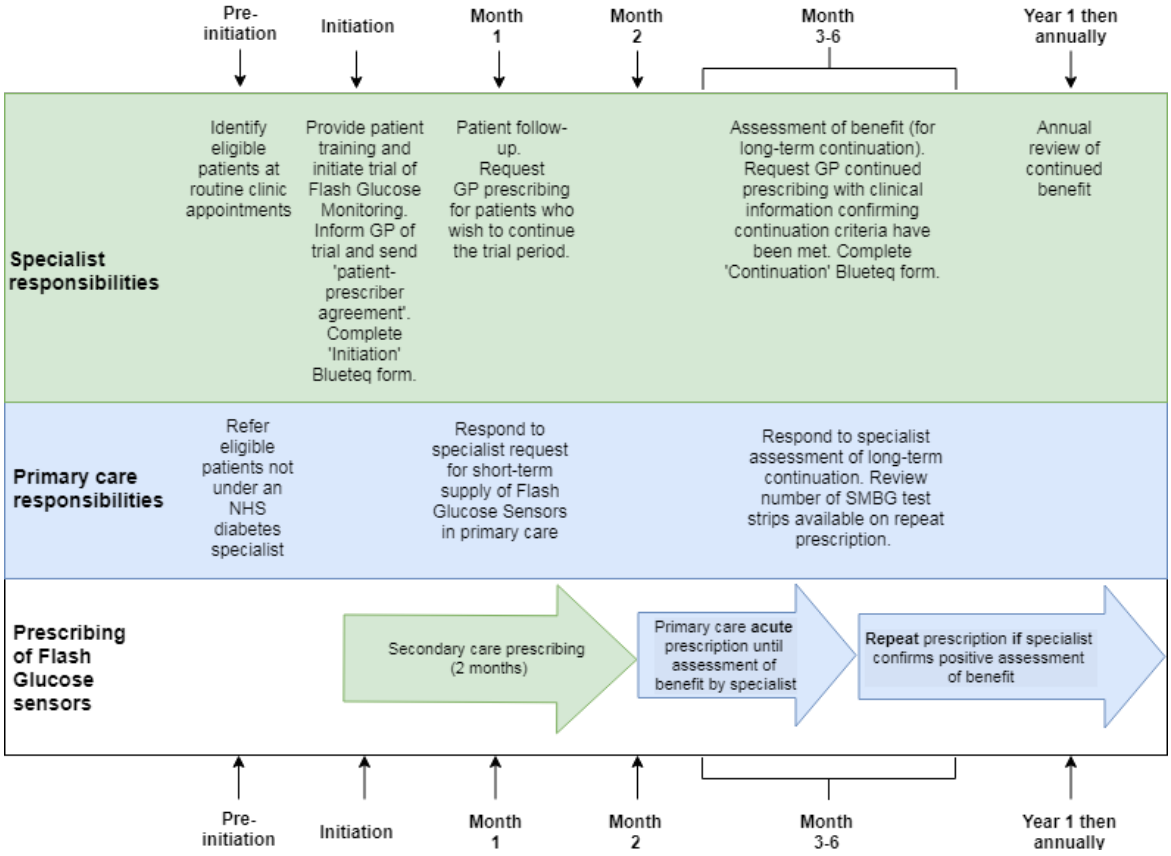
Eligibility criteria for NHS funding of Flash Glucose Monitoring

Assessment and initiation of patients on Flash Glucose Monitoring will be done by **NHS diabetes specialist teams ONLY** for the following patients:

1) The person has type 1 diabetes and tests frequently (more than 8 times per day as demonstrated on a meter download/review over the past 3 months) AND where the use of flash may facilitate a safe reduction in test strip usage of 8 or more a day (7 or more a day in children aged 0-19 years)
2) The person has any form of diabetes on haemodialysis and on insulin treatment and tests frequently (>8 times per day) AND where the use of flash may facilitate a safe reduction in test strip usage of 8 or more a day (7 or more a day in children aged 0-19 years)
3) The person has diabetes associated with cystic fibrosis on insulin treatment
4) The person has type 1 diabetes and is pregnant (12 month approval only)
5) The person has type 1 diabetes and is on multiple daily injection (MDI) or insulin pump therapy where conventional monitoring is not possible with SMBG testing due to disability, occupational or psychosocial reasons
6) The person has type 1 diabetes and impaired awareness of hypoglycaemia or recurrent severe hypoglycaemia, and their clinician considers that a Flash Glucose Monitoring system would be more appropriate than other evidence-based interventions for the individual's specific situation
7) The person has type 1 diabetes, previously self-funded a Flash Glucose Monitoring system, meets one of the above criteria and has shown improvement in HbA1c since self- funding

The NHS diabetes specialist teams will be responsible for monitoring and recording the effectiveness of Flash Glucose Monitoring; a data collection form has been built into the Blueteq forms to support this. If a GP has concerns about effectiveness of Flash Glucose Monitoring for an individual patient they should contact the NHS specialist diabetes team.

Summary



Responsibilities for GPs

- Referrals:
  - Do not refer patients with type 1 diabetes who are already under an NHS diabetes specialist service for the sole purpose of initiation of Flash Glucose Monitoring, they will be seen in time at their next routine appointment.
  - Only refer patients who meet eligibility criteria who are not under the care of an NHS diabetes specialist service who request Flash Glucose Monitoring, or who may benefit from the device, provided you feel the patient fulfils the NHS eligibility criteria.
- Prescribing:
  - Do not initiate Flash Glucose Monitoring for any patient. Initiation should be carried out by the NHS specialist diabetes team. Patients will obtain their first 2 months supply of Flash Glucose Monitoring from the NHS specialist diabetes clinic.
  - Only prescribe Flash Glucose Monitoring sensors if the patient's NHS diabetes specialist team has confirmed the patient meets the approved eligibility criteria (this includes new patients and patients who were already self-funding).
  - Sensors that fall off/malfunction **should not** be replaced on prescription – Abbott should be contacted directly by the patient and they will send out a replacement.
  - Review the number of SMBG test strips available on repeat in line with recommendations from the diabetes specialist and/or after discussion with their patient (patients who previously used high numbers of strips should see a reduction in strip use)
- Expected communication from NHS specialist diabetes team to GP:
  - At initiation: Notification via clinic letter of patient eligibility, trial initiation and expected patient outcomes. A copy of the patient-prescriber agreement will be provided.
  - After Month 1: Request primary care prescribing for patients who are tolerating Flash Glucose Monitoring and wish to continue the trial period (hospital will supply the first 2 months supply).
  - At assessment for long term continuation (typically 3-6 months):
    - If trial successful: Request for GP to continue prescribing Flash Glucose Monitoring with clinical information confirming that the continuation criteria has been met
    - If trial unsuccessful: Request for GP to discontinue prescribing Flash Glucose Monitoring .
  - Annually thereafter: Notification of confirmation of continued benefit following annual review
- Training:
  - Learn about the FreeStyle Libre system; a one page summary is available
  - Recommended competencies for GPs continuing Freestyle Libre prescriptions are available via the London Diabetes Clinical Network (LDCN) website.
  - Patients unable to effectively use the device should be referred back to the initiating NHS diabetes specialist team

Responsibilities for NHS diabetes specialists

- Initiation:
  - Initiate in accordance with the North Central London criteria for flash glucose monitoring; including patient-prescriber agreement and 'initiation' Blueteq form
  - Send a copy of the patient-prescriber agreement to the patient's GP
  - Provide GPs with the expected number of SMBG strips to be used per month
  - Provide patient with training and information, and ensure they are competent to use Flash Glucose Monitoring
  - Provide Flash Glucose Monitoring handset, sensor starter pack and one additional sensor at initiation
- Supplying sensors
  - Supply sensors for the first 2 months of treatment
- Clinic review
  - Monitor and review progress of clinical outcome criteria as described for the individual patient for 6 months after initiation of Flash Glucose Monitoring
  - Discontinue Flash Glucose Monitoring if the agreed benefits and outcomes not achieved at 6 months or if patient DNA clinic appointments for review.
  - Complete 'continuation' Blueteq form for all patients (including those who should not continue) so this data is captured and can be analysed
- Communication to GP:
  - On initiation: Notify the GP of patient eligibility, trial initiation and expected patient outcomes. Include a copy of the patient-prescriber agreement.
  - After Month 1: Request short term prescribing by the GP for patients who are tolerating Flash Glucose Monitoring and wish to continue the trial period from Month 2.
  - At assessment for long-term continuation: Notify the GP with the outcome and detail whether the patient requires long-term prescribing of Flash Glucose Monitoring in primary care.
  - At any time point: Notification of confirmation of continued benefit following annual review or prompt communication with the GP if treatment is changed
- For patients who met the approved eligibility criteria, have self-funded Flash Glucose Monitoring and have shown improvement in HbA1c, it is reasonable to ask their GP to take on long-term prescribing without a hospital supply. In such cases, specialists should complete the 'continuation' Blueteq forms and notify the GP for long-term prescribing in primary care.

Responsibilities for patients / carers

- Understand their responsibilities as outlined in the patient-prescriber agreement
- Wear the sensor continuously and scan at least 8 times per day and use the sensor >70% of the time
- Participate in follow up clinic or telephone appointments as scheduled by the specialist.
- Inform the NHS diabetes specialist clinic if they have any problems in the use of Flash Glucose Monitoring
- Contact Abbott customer care for a replacements sensor if it falls off within 14 days or malfunctions

Document control

Date	Version	Amendments
Oct 2017	1.0	New guidance + FAQ
May 2018	2.0	Updated in response to RMOC guidance
Dec 2018	3.0	Updated in response to LDCN/LPP v1.0 guidance
June 2019	4.0	Updated in response to NHS England 'Flash Glucose Monitoring: National Arrangements for Funding of Relevant Diabetes Patients' (LDCN/LPP v2.0 guidance)

Document management

Groups / Individuals who have overseen the development of this guidance:	Haringey CCG, Barnet CCG, Camden CCG, NCL JFC Support
Groups which were consulted and have given approval:	NCL Libre Working Group, NCL CCGs
File name:	NCL Flash Glucose Monitoring_Position Statement_V3.0_FINAL.Docx
Version number:	V4.0
Available on:	NCL MON website
Disseminated to:	All Trusts and CCGs in NCL
Equality impact assessment:	Low
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